Applicant: Schwartz et al.
Serial No.: 10/665,788
Group Art Unit: 3738

PATENT
Docket No.: 20220-502

REMARKS

This Amendment is filed in response to the Office Action dated September 17, 2004. In this Amendment, claims 1-2, 10-12, and 16 are amended, claim 17 canceled (without prejudice or disclaimer) and new claim 18 is added. Upon entry of this amendment, claims 1-16 and 18 shall be pending and awaiting further examination. Of these claims, claims 1 and 12 are independent.

In the Office Action, claims 1-17 have been rejected based on prior art grounds and grounds under 35 U.S.C. § 112. For the reasons set forth below, these rejections are hereby traversed. Moreover, it is respectfully submitted that this Amendment resolves all remaining issues, thus placing all pending claims in condition for allowance. Hence, it is submitted that entry of this Amendment is proper.

Claim Rejections under 35 USC § 112 second paragraph

The Examiner rejected claims 1 and 12 stating:

> Regarding claim 1, "sealed membrane forming an inner chamber" is not understood. Is there an element (membrane) which completely closes the inner chamber? If so, it is not shown. Or is the device open, such as a balloon? Similar for claim 12.

The Applicant does not concede the rejection. However, to advance the prosecution of this application, claims 1 and 12 have been amended to clarify the claimed invention. Claim 1 now recites "a sealed membrane forming an inner cavity." Claim 12 now recites an "elastic member defining an inner cavity containing a medium". As disclosed in a preferred embodiment in the specification at paragraphs 0081-0089, as well as in Figures 8 and 9, the membrane is a single, sealed, continuous membrane that defines an inner cavity whereby the device functions to transfer fluid between an inner chamber and an outer chamber of the inner cavity relative to the location of these chambers inside

or outside of the body lumen. If the membrane was not sealed, the fluid could not be contained within the inner cavity. In other words, as recited in both claims 1 and 12, the inner cavity results from the membrane being sealed.

In view of the foregoing, it is submitted that any indefiniteness that existed in the claims is no longer present. It is therefore requested that the rejections based on indefiniteness under 35 USC § 112 be withdrawn.

Claim Rejections under 35 USC § 112 first paragraph.

The Examiner wrote:

> The disclosure fails to describe or show the exact configuration of sealed membrane as described in the rejection above. As shown, blood would enter the chamber and coagulate.

The Applicant respectfully submits that the Examiner is misreading the Figures and/or the specification. Referring to Figures 8 and 9, there are shown devices 600 and 700 which each comprise a completely sealed, balloon-like device as described in paragraphs 0081-0089 of the specification. These balloon-like devices are completely sealed and pass through an opening formed in the body lumen. That portion of the device disposed outside of the lumen constitutes the outer chamber 603, 703 of the device and that portion on the inside of the lumen constitutes the inner chamber 604, 704 of the device. The inner chamber and outer chamber together constitute the single inner cavity of the device, wherein the cavity contains a medium which flows between the two chambers depending on pressures present in, e.g. the descending aorta. If the devices 600 and 700 where removed from the body, they would appear as completely sealed bladders filled with a medium. In view of this explanation it is submitted that the rejection under § 112, 1st paragraph, cannot properly stand. Hence, withdrawal of the rejection is respectfully requested.

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Claim Rejections under 35 USC § 102

The examiner rejected claims 1-2, 4-6, 8-10, 12-13, and 15-17 under § 102(b) as being anticipated by *Brockway et al.* The Applicant respectfully disagrees.

Claim 1, as amended, is not anticipated by *Brockway* for the following reasons:

1. *Brockway* cannot be properly described as disclosing a device for treating an elevated lumen pressure condition in a patient as claimed herein. More specifically, the *Brockway* device is a diagnostic tool for reading the pressure in a body lumen, not a device for treating pressure in a body lumen as in the presently claimed invention. Furthermore, these two functions appear to be mutually exclusive in the context of using a medium encased in a membrane within the body lumen. If the function of the device is blood pressure monitoring (as in *Brockway)*, then any change in blood pressure that is caused by movement of the device (as in the present invention) would result in a false reading by the *Brockway* device. Similarly, if the device of the present invention were modified to include a transducer, as is disclosed in some of the embodiments, the transducer would be reading the reduced pressure in the lumen, not the natural pressure that the *Brockway* device intends to measure.

2. *Brockway* does not disclose a medium dispensed in an inner cavity, the inner cavity having a portion sized for placement external to said body lumen as claimed. *Brockway* uses its medium only to transfer pressure to its transducer. In other words, the presently claimed invention recites that a portion of the inner cavity be external of the body lumen so that the medium may be transferred outside the lumen in order to relieve pressure inside the lumen. If *Brockway* was designed this way, it would not accomplish its function of taking accurate pressure readings inside the lumen. Indeed, a close look at the Figures in *Brockway* shows the transducer pressed right up against the wall of the lumen.

That a small amount of medium may indeed be external to the lumen in *Brockway* falls short at least of disclosing a "...portion sized for placement external to said body lumen..." as claimed.

3. *Brockway* does not disclose a sealed membrane forming an inner cavity as in the claimed invention. Instead, *Brockway* uses an encapsulated medium to transfer pressure to a pressure transducer. The pressure transducer is exposed to the medium and therefore the membrane does not form an enclosed inner cavity. Rather, the transducer itself defines a portion of the inner cavity.

Claim 12, as amended, is not anticipated by *Brockway* for the following reasons:

1. *Brockway* does not disclose a method for dampening pressure fluctuations in a body lumen. At best, *Brockway* discloses a way merely of measuring arterial and coronary blood pressures. In no way does *Brockway* teach dampening the pressure fluctuations in a body lumen as claimed. Indeed, any such dampening in the *Brockway* device would render the *Brockway* device useless for it's intended purpose.

2. *Brockway* does not disclose moving a volume of medium from an internal portion of the elastic member to the external portion of the elastic member in response to an increase in pressure within said body lumen, thereby therapeutically dampening pressure fluctuations in the body lumen as claimed. In fact there is no teaching whatsoever in *Brockway* suggesting movement of fluid to an area external of the body lumen. As argued above, only enough fluid to communicate a pressure fluctuation to the pressure transducer is required by the *Brockway* device. And if an incompressible fluid is used, this volume is nearly zero. And by no means is a therapeutic effect obtained in any event.

In light of the above arguments, the Applicant respectfully submits that the Examiner's § 102(b) rejections cannot be properly maintained. Hence, withdrawal of the rejections is requested.

Rejections under § 103

The Examiners rejections under § 103(a) apply to claims 3, 7, and 14. Applicant respectfully submits that the claims from which these rejected claims depend are now in condition for allowance for at least the reasons stated above. However, these claims further define the invention and are thus independently patentable. Nonetheless, the Examiner argues:

> *Brockway* et al teaches the device as described above however, fails to teach using a gas but teaches a low viscosity liquid (paragraph 46) or urethane but teaches polymer materials for element 34; see paragraph 56. Lacking any criticality in the specification the use of a gas or urethane in lieu of that used by *Brockway* et al. produces no advantage and is considered an obvious matter of design choice to one skilled in the art.

At a minimum, this rejection is traversed because there is no motivation to look to *Brockway*. *Brockway* is a diagnostic tool, not a therapeutic device and thus teaches away from the claimed invention.

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CONCLUSION

In view of the foregoing, it is submitted that all claims pending after entry of this amendment (namely, claims 1-16 and 18) are in condition for allowance. Hence, entry of this Amendment is proper and is earnestly requested.

If any questions or issues arise that are more easily addressed by the Examiner through direct communication with the undersigned, the Examiner is cordially to contact the undersigned at the number listed below.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,

Dated: JAN 18, 2005

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